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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,832	12/30/2003	Heinz Redl	20695C-003420US	9378

44444 7590 02/18/2005

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,832	REDL ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20031230*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Sequence Listing filed December 30, 2003 is approved.

2. Claims 13-16 are objected to because of the following informalities: At claim 13, line 4, the comma should be deleted and the word "and" inserted in its place. Appropriate correction is required.

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 13, 14, 16-18, and 21-23 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 and 8-10, respectively, of prior U.S. Patent No. 6,506,365. This is a double patenting rejection.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-8, 11, 12, 15, 19, and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No.

6,506,365. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '365 patent anticipate the instant claims 1-8, 11, 12, 19, and 20. With respect to instant claim 15, while the '365 patent claims in its kit an agent capable of processing fibrinogen to fibrin, the '365 patent does not explicitly claim a thrombin preparation as this agent. It would have been obvious to one of ordinary skill in the art to use a thrombin preparation as the agent capable of processing fibrinogen to fibrin claimed in the '365 patent because thrombin preparations are known in the art and are known to possess this function claimed in the '365 patent, and because the substitution of a known species for a genus is prima facie obvious.

6. Claims 1-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,713,453. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '453 patent anticipate the instant claims.

7. The effective filing date of instant claims 1, 5-8, and 13-23 is deemed to be September 25, 2000, the filing date of grandparent application 09/669,240. Instant claims 1, 5-8, and 13-23 are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the '240 grandparent application because the '240 grandparent application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

The effective filing date of instant claims 2-4 and 9-12 is deemed to be September 25, 2001, the filing date of parent application 09/963,156. Instant claims 2-4 and 9-12 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/669,240 because the '240 grandparent application, under the test of 35 U.S.C.

112, first paragraph, does not disclose a fibrin/fibrinogen-binding moiety which is a nucleic acid or a $VEGF_{165}$ C-terminal domain, does not disclose a substance capturing moiety which is a receptor or a part thereof, does not disclose a pharmaceutically active substance which is a wound-healing substance, and does not disclose a conjugate which is a recombinant fusion protein. Accordingly, U.S. Patent No. 6,506,365, which issued based upon the '240 grandparent application and which has a different inventorship than the instant application, is available against instant claims 2-4 and 9-12 as prior art under 35 U.S.C. 102(e).

8. Claims 2-4, 11, and 12 are directed to an invention not patentably distinct from claims 1-22 of commonly assigned U.S. Patent No. 6,506,365. Specifically, see the above obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,506,365, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly

assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 2-4, 11, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,506,365. See the above obviousness-type double patenting rejection.

11. Claims 7-9, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gold et al. Gold et al teach therapeutic agents or detectable labels conjugated to fibrin-binding peptides derived from fibronectin. The conjugate can be in the form of a recombinant hybrid molecule, i.e. a recombinant fusion protein, and the therapeutic agents include growth factors. See, e.g., the Abstract; column 30, lines 5-32; and claims 8-12. Note that instant claim 7 does not require the presence of a substance capturing moiety.

12. Claims 1 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenberg. Goldenberg teaches conjugates comprising antibodies to fibrin covalently linked to a chelating agent which complexes with an imaging agent. The antibodies can be conjugated to the chelating agent through a linker. See, e.g., column 8, lines 31-37; column 10, line 34-column 11, line 5; column 11, lines 35-52; and claims 1, 7, 22, and 24.

13. Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyle et al. Boyle et al teach a receptor-plasmin complex conjugated to an antibody for fibrin. See column 23, lines 35-44.

14. Claims 1 and 3-7 are rejected under 35 U.S.C. 102(b) as being anticipated by the Kurokawa et al article. The Kurokawa et al article teaches a bispecific antibody which binds both to fibrin and to tPA. A complex of the tPA and the bispecific antibody is administered in vivo in order to lyse clots. See, e.g., the Abstract; page 1163, column 2, second full paragraph; and page 1164, column 2, first full paragraph.

15. Claims 1, 2, and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Reno et al. Reno et al teach tPA labeled with a chelated radiolabel via a linker. See, e.g., column 5, lines 20-56, and column 8, lines 34-48.

16. Claims 7, 8, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 99/40947. The WO Patent Application '947 teaches $VEGF_{165}$ radiolabeled with ^{125}I and with Tc-99m. See, e.g., page 30, line 1, and page 39, line 15. The radiolabels constitute imaging agents. Note that instant claim 7 does not require the presence of a substance capturing moiety.

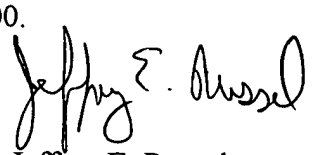
17. Claims 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 96/06641. The WO Patent Application '641 teaches pharmaceutically active substances linked, either directly or via a linker, to VEGF. The conjugates can be prepared as a chimera using the techniques of recombinant DNA, i.e. can be recombinant fusion proteins. Examples are $VEGF_{165}$-SAP, and VEGF conjugated to nucleic acids See, e.g., the Abstract;

page 4, lines 21-26; and page 23, line 4 - page 31, line 23. Note that instant claim 7 does not require the presence of a substance capturing moiety.

18. Claims 7, 8, 11, and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Stephens et al. Stephens et al teach radiolabeled nucleic acids which bind to fibrin clots. See, e.g., column 19, lines 30-36, and column 21, lines 17-43. The radiolabels constitute imaging agents. Note that instant claim 7 does not require the presence of a substance capturing moiety.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

February 14, 2005